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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,599	09/26/2003	Kenneth Reever	BSC-157DV	1962
30636	7590	04/05/2005	EXAMINER	
FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038			BOGART, MICHAEL G	
		ART UNIT		PAPER NUMBER
				3761

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

4/5

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/672,599	REEVER, KENNETH
	Examiner	Art Unit
	Michael G. Bogart	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 14 March 2005.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 18-23 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 20,21 and 29-34 is/are allowed.
- 6) Claim(s) 18,19 and 23 is/are rejected.
- 7) Claim(s) 22 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

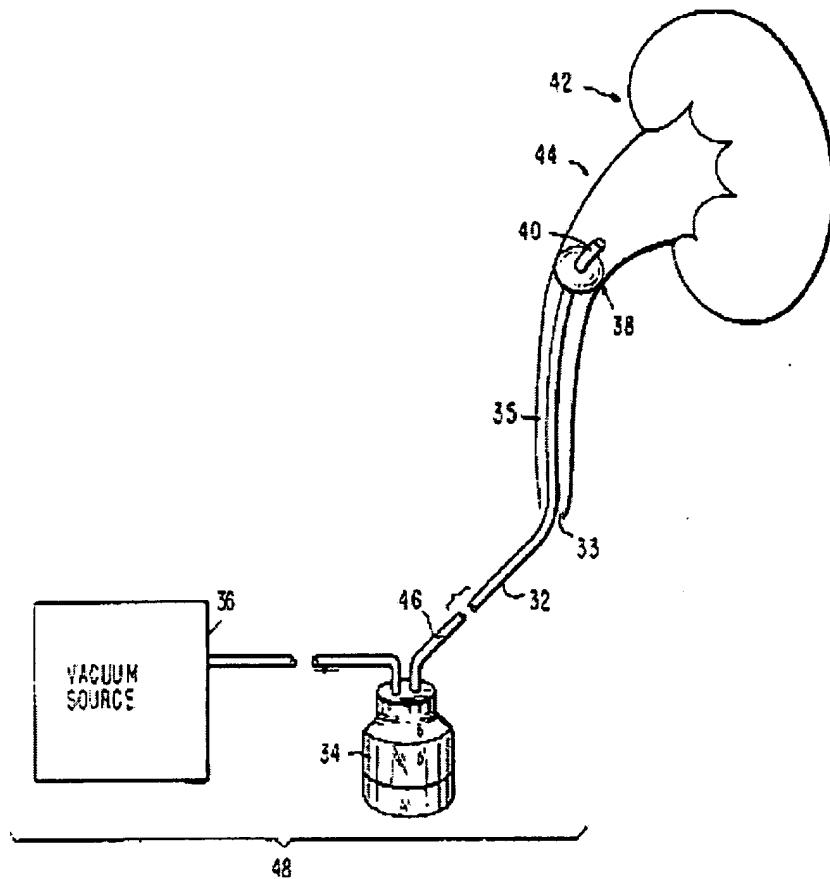
Claims 18 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ikeguchi (US 6,500,158 B1).

Ikeguchi teaches a first catheter (32) positionable in a patient's first ureter (35), the first catheter (32) having a proximal and a distal end (40, 46), the proximal end (40) of the catheter (32) including a ureter to catheter seal (38), the distal end (46) of the catheter capable of passing through the patient's urinary sphincter, the distal end (46) of the catheter capable of being connected to an external urine collector (34)(see fig. 2, below).

Ikeguchi expressly discloses the claimed invention except for there being two catheters, one for each ureter of a patient.

Generally, mere duplication of parts is not sufficient to patentably distinguish an invention from the prior art unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a "web" which lies in the joint, and a plurality of "ribs" projecting outwardly from each side of the

web into one of the adjacent concrete slabs. The prior art disclosed a flexible water stop for preventing passage of water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.). MPEP § 2144.04 VI (B).



In the present case, it would have been obvious to one of ordinary skill in the art to modify the system of Ikeguchi to include two catheters in order to provide for patients who need simultaneous treatment of both ureters.

Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ikeguchi as applied to claim 18 above, and further in view of Willingham (US 5,411,495 A).

Ikeguchi does not disclose a valve.

Willingham teaches a conventional urine catheter including a valve (62) between the distal end of the catheter (16) and the patient's urethra (fig. 1). The one way valve prevents backflow of urine to the urethra. At the time of the invention, it would have been obvious to one of ordinary skill in the art to add a valve to the distal end of the catheter of Ikeguchi in order to prevent backflow.

Claim 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ikeguchi as applied to claim 18 above, and further in view of Bosley (US 5,289,831 A).

Ikeguchi does not disclose the specific type of material from which the catheters are constructed.

Bosley teaches catheters, stents and the like which are constructed from polyethylene, polypropylene and other suitable materials which are medical grade and can readily be made sterile (col. 12-line 47-col. 13, line 40).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to select one of the exemplary materials of Bosley to construct the catheters of Ikeguchi in order to provide proven, readily available medical grade construction.

***Allowable Subject Matter***

Claims 20, 21 and 29-34 are allowed.

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 20, 21, 30 and 32-34, no art of record teaches 1<sup>st</sup> and 2<sup>nd</sup> catheters extending from the 1<sup>st</sup> and 2<sup>nd</sup> ureters of a patient, the catheters including ureter seals, the ends of the catheters both attached to a third catheter which is in turn connected to an external collection container.

Regarding claims 29 and 31, the closest art of record, Ikeguchi, teaches catheter systems that extend through the urinary system, while the instant invention uses direct surgical incisions to access the ureters.

Regarding claim 22, Ikeguchi does not teach any kind of adhesive used in conjunction with inflatable seal (38).

#### ***Response to Arguments***

Applicant's arguments filed 14 March 2005 have been fully considered but they are not persuasive.

Regarding claim 18, in response to applicant's argument that there is no suggestion to modify the reference, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicants assert that Ikeguchi fails to teach or suggest the use of the claimed method or apparatus on more than one kidney and that the reference provides no motive for such a modification. Applicants further assert that the reference does not suggest that adding a second catheter would be more effective or would not be harmful.

Ikeguchi teaches all of the claimed structure for treating a single kidney. In instances where both kidneys required treatment, one of ordinary skill in the art would have been motivated to apply the apparatus taught by the reference to each kidney. If both kidneys required treatment at the same time, it would have been obvious to provide a catheter to each kidney simultaneously.

As cited above, mere duplication of parts will not support patentability absent a showing of a new and unexpected result. Applicants do not assert that a new and unexpected result is achieved by duplicating the catheters and placing one in each of a patient's ureters. Applicants also do not show how applying the device of Ikeguchi to each kidney at that same time would be harmful, nor is there any teaching in the reference that such use would be detrimental to a patient.

Applicants have not presented arguments specifically directed to claims 19 and 23.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Larry Schwartz may be reached at phone number (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart  
28 March 2005



Larry I. Schwartz  
Supervisory Patent Examiner  
Group 3700